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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,655	11/15/2001	Lynne Canne	03504.284B	7459
7590 06/30/2004			EXAMINER	
LINIAK BERENATO LONGACRE & WHITE, LLC			GUPTA, ANISH	
SUITE 240			ART UNIT	
6550 ROCK SPRING DRIVE			PAPER NUMBER	
BETHESDA, MD 20817			1654	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/987,655	Applicant(s) CANNE ET AL.	
	Examiner Anish Gupta	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27 and 29-60 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 27 and 29-60 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11-2001</u> . | 6) <input type="checkbox"/> Other: ____. |

1. Applicants amendment filed, 11-15-01, is acknowledged. Claims 1-26 and 28 were canceled, claim 27 was amended, and claims 29-60 were added to instant application. Claims 27, 29-60 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 27 and 29-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to an apparatus for producing assembled peptides. However, it is unclear what components qualify as the apparatus. Applicants claims imply that the resin bound peptide is the apparatus. However, in peptide chemistry, apparatus are conventionally known in the art to be automated synthesizers and the like, not resin bound peptides themselves. Further, resin bound peptides also do not fall within dictionary definition of apparatus. For example, the Cambridge International Dictionary defines apparatus as "a set of equipment or tools or sometimes a machine which is used for a particular purpose." A resin or resin bound peptide does not qualify as a "equipment," "tool," or "machine" and as such cannot be seen as an apparatus. Finally, in the Manual of Classification in Class 435, Sub-class 283.1+, although not controlling on the issue, does sub-classify a resin as an "apparatus." Thus, the claim is indefinite with respect to apparatus.

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Moreover, it is unclear however, the set of second partially or completely unprotected peptides recited in (b) are part of the apparatus and if so how they are associated with the "apparatus." In reading the claims, the peptides of (b) and (c) are not part of the "apparatus" but are an separate from the apparatus that is the solid support bound peptide of part (a). Thus, the claims is unclear as to the relationship of components (b) and (c) to the apparatus.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 27, 29-60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. Patent No. US 6,326,468.

Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims of the instant application are drawn to an apparatus for producing assembled polypeptides comprising a solid support having bound thereto a partially or completely unprotected polypeptide wherein the peptide is bound to the solid support via the N-terminus and the peptide has a C-terminal end of a thioacid or thioester of the formula $-\text{COSR}$ (see claim 1 and 41). The US Patent claims a method for producing polypeptides comprising binding a partially or completely

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unprotected first peptide segment to a solid phase via a linker to form a solid phase bound peptide segment, wherein the peptide segment is bound to the solid support via the N-terminus using a linker, similar to the claimed invention, and the peptide has a C-terminal end of a thioacid or thioester of the formula $-\text{COSR}$ (see claim 1). Note that the modifications and/or characteristics defined in the subsequent claims of the instant application are similar to the characteristics defined in the US Patent. For example, claims 36-40 of the instant application disclose similar features to claims 8-11 of the US patent in the type of solid support used, the length of peptide segments, the source of the peptide, and the type of backbone in the peptide (natural vs. non-natural). The difference between the US Patent and the instant application is that the US Patent does not claim a "apparatus." However, in practicing the claimed invention of the US Patent, one would have to bind a partially or completely unprotected first peptide segment to a solid phase via a linker to form a solid phase bound peptide segment, wherein the peptide segment is bound to the solid support via the N-terminus using a linker, similar to the claimed invention, and the peptide has a C-terminal end of a thioacid or thioester of the formula $-\text{COSR}$. In achieving this aspect of the invention, one would necessarily obtain an apparatus similar to the claimed invention. Note that the claimed invention implies that the apparatus is a solid support bound peptide. Further, the claimed invention of the apparatus cannot be used to practice any other method other than that disclosed in the US Patent because the apparatus has the same components as the method disclosed in the US Patent. Thus, the claimed invention the US Patent and the instant application are obvious variants of one another and are not patentably distinct from each other.

Claims 27, 29-60 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-26, 29-56 of copending

Application No. 09/987675. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reason.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


The claims of the instant application are drawn to an apparatus for producing assembled polypeptides comprising a solid support having bound thereto a partially or completely unprotected polypeptide wherein the peptide is bound to the solid support via the N-terminus and the peptide has a C-terminal end of a thioacid or thioester of the formula $-\text{COSR}$.

The US provisional application discloses a kit for producing assembled polypeptides comprising a solid support having bound thereto a partially or completely unprotected polypeptide wherein the peptide is bound to the solid support via the N-terminus and the peptide has a C-terminal end of a thioacid or thioester of the formula $-\text{COSR}$. The claims of the provisional application are identical to the instant application except that the provisional application recites a "kit" and "containers" whereas this application recites an "apparatus." Since the US provisional application discloses the same components that are deemed to be an apparatus in this application, i.e. a resin bound polypeptide for chemical ligation, the provisional application discloses the apparatus of the claimed invention. In practicing the claimed invention of the provisional application, one would have to bind a partially or completely unprotected first peptide segment to a solid phase via a linker to form a solid phase bound peptide segment, wherein the peptide segment is bound to the solid support via the N-terminus using a linker, similar to the claimed invention, and the peptide has a C-terminal end of a thioacid or thioester of the formula $-\text{COSR}$. In achieving this aspect of the invention, one would necessarily obtain an apparatus similar to the claimed invention. Note that the claimed invention implies that the apparatus is a solid support bound peptide.

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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can normally be reached on (571) 272-0961. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Anish Gupta
Patent Examiner